

TECHNICAL MEMORANDUM



TO: Dennis Crumpler / OAQPS
FROM: Eric Boswell / NAREL
COPY: Dr. R.K.M. Jayanty, RTI
AUTHOR: Jewell Smiley / NAREL
DATE: November 4, 2005
SUBJECT: RTI Laboratory Audit

Introduction

On July 12, 2005, a laboratory audit was conducted at the Research Triangle Institute (RTI) as part of the QA oversight for the PM_{2.5} Speciation Trends Network (STN). RTI is the prime contractor providing analytical services to support over two hundred field sites collecting speciation samples. The US EPA audit team included Eric Boswell and Jewell Smiley from the National Air and Radiation Environmental Laboratory (NAREL) with Dennis Crumpler and Joann Rice from the Office of Air Quality Planning and Standards (OAQPS). Solomon Ricks and Jeff Lance were also present during the audit as EPA observers. This audit was a routine annual inspection of the laboratory systems and operations required for acceptable contract performance.

Summary of Audit Proceedings

After a brief meeting with the RTI senior staff and supervisors, the audit team separated as necessary to complete specific assignments for the audit process. At least one member of the RTI staff was always available to escort and assist each auditor. The following specific areas on the RTI campus were visited and inspected.

- ✓ Gravimetric Laboratory - Ms. Lisa Greene
- ✓ Organic Carbon/Elemental Carbon (OC/EC) Laboratory - Dr. Max Peterson
- ✓ X-ray Fluorescence (XRF) Laboratory - Dr. William Gutknecht, Ms. Andrea McWilliams
- ✓ Ion Chromatography (IC) Laboratory - Dr. Eva Hardison
- ✓ Sample Handling and Archiving Laboratory (SHAL) - Mr. Jim O'Rourke

Besides the areas mentioned above, interviews were conducted with the following RTI staff.

- ✓ Dr. R.K.M. Jayanty - RTI Services Program Manager
- ✓ Dr. Jim Flanagan - Quality Assurance Manager

✓ Mr. Ed Rickman - Data Management Technical Supervisor

RTI has been analyzing samples from the PM_{2.5} STN since the network began in February of 2000. Members of the audit team were familiar with RTI's current Quality Assurance Project Plan (QAPP) and pertinent SOPs. A report from the previous year's on-site audit was available for reference and followup [see reference 1]. Also available was a 119-page report prepared by RTI which summarized the quality control data and corrective actions during the period July 1 through December 31, 2004. RTI was one of several laboratories to participate in a Performance Evaluation (PE) study earlier in 2005 [see reference 2], and results from that PE study were discussed with RTI staff during the audit. Several experimental activities were also performed during the course of this audit which will be described later within the appropriate section of this report.

Gravimetric Laboratory

The gravimetric laboratory is equipped with two weighing chambers located in building 11. Ms. Lisa Greene is the supervisor of this lab, and she was interviewed by Jewell Smiley and Joann Rice with Solomon Ricks observing. The interviews and inspections were performed to determine compliance with good laboratory practices, the QAPP, and the following SOPs.

- *Standard Operating Procedure for PM_{2.5} Gravimetric analysis* [see reference 3]
- *Standard Operating Procedures for Procurement and Acceptance Testing of Teflon, Nylon, and Quartz Filters* [see reference 4]

Both of the weighing chambers are configured to satisfy conditions of cleanliness, constant temperature, and constant humidity required by the program. Accurate control of climate inside the weighing chamber is important because balance calibration is very sensitive to temperature, and the equilibrated mass of an air filter sample is sensitive to humidity. Mass determination typically proceeds by weighing the Teflon® collection filter before and after the sampling event. The amount of Particulate Matter (PM) captured onto the surface of the filter can be calculated by a simple subtraction of the tare weight from the loaded filter weight.

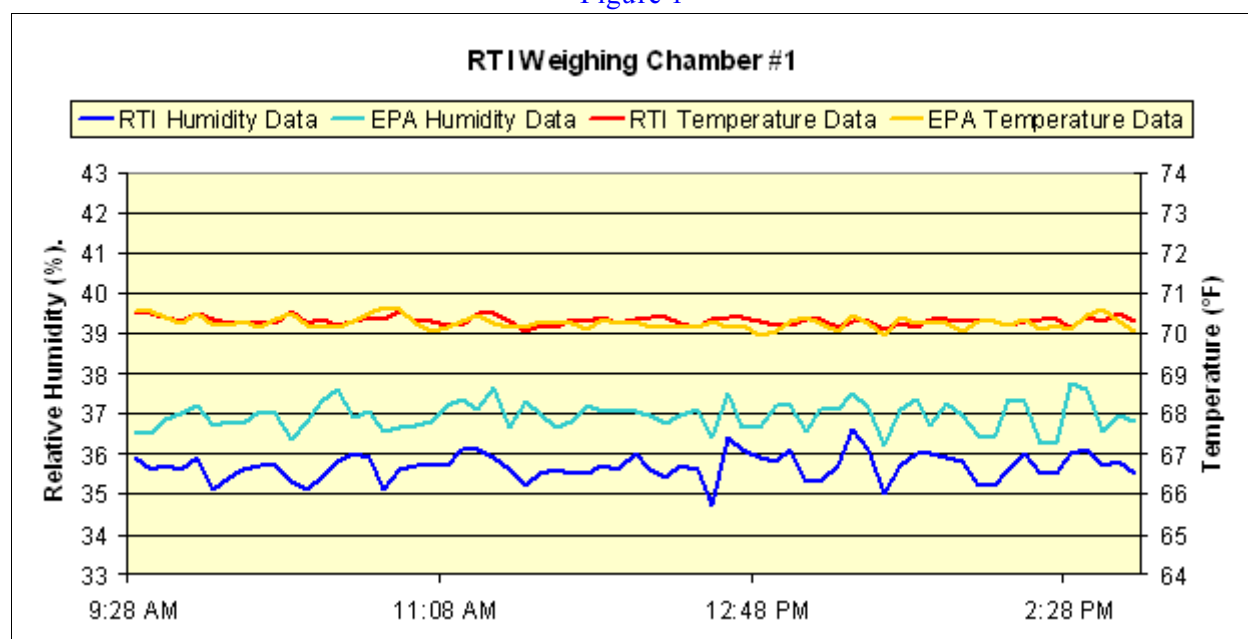
A few items were hand-carried to the audit from NAREL so that experimental measurements could be made during the audit. Two metallic weights and four Teflon® filter samples were presented to Lisa with a request to weigh each item at least twice during the day. It should be explained that two of the filter samples were loaded with PM_{2.5} captured from the Montgomery air in January of 2005 and two filters were blank. Metallic weights were included in the sample set to represent a very stable reference material for measuring gravimetric mass. All of the test samples were placed into Chamber #1 and given approximately one hour to equilibrate before the first weighing session was performed. Mr. Maurice Gerald was the analyst selected to perform the work using microbalance "C" for all of the measurements. Results are presented in Table 1 along with mass values previously determined at NAREL. Maurice was able to weigh the test samples four times with about an hour separating each weigh session. Table 1 shows good inter-laboratory agreement for all three sample types.

Table 1. Gravimetric Mass Determinations

Sample ID	Sample Description	NAREL Value Determined on July 7 (mg)	All RTI Values Determined on July 12			
			~11 AM (mg)	~12 AM (mg)	~1 PM (mg)	~2:30 PM (mg)
MW05-11331	metallic wt.	97.546	97.545	97.545	97.545	97.545
MW05-11332	metallic wt.	192.422	192.421	192.421	192.421	192.420
T05-11317	loaded filter	142.486	142.482	142.482	142.482	142.483
T05-11318	loaded filter	142.826	142.823	142.823	142.824	142.824
T05-11322	blank filter	141.665	141.663	141.663	141.664	141.664
T05-11323	blank filter	145.708	145.705	145.705	145.705	145.705

Two Dickson data loggers were also carried to the audit from NAREL so that independent measurements of temperature and humidity could be recorded during the audit. One of the data loggers was placed into each weighing chamber immediately near RTI's device for measuring the temperature and humidity. Measurements were downloaded from all of the devices at the end of the day, and these data are presented in Figure 1 and Figure 2. Figure 1 shows good agreement between the temperature loggers placed into Chamber #1, but less agreement was observed for the humidity readings. The graph shows that humidity values measured by RTI's device were consistently lower by a small amount. The average relative humidity (RH) recorded by NAREL's device was 36.9 %, and the average RH recorded by RTI's device was 35.7 % during the same period. Both data loggers had an expected accuracy of ± 2 % RH. All of the measurement differences shown in Figure 1 are within the stated accuracy of each logging device.

Figure 1



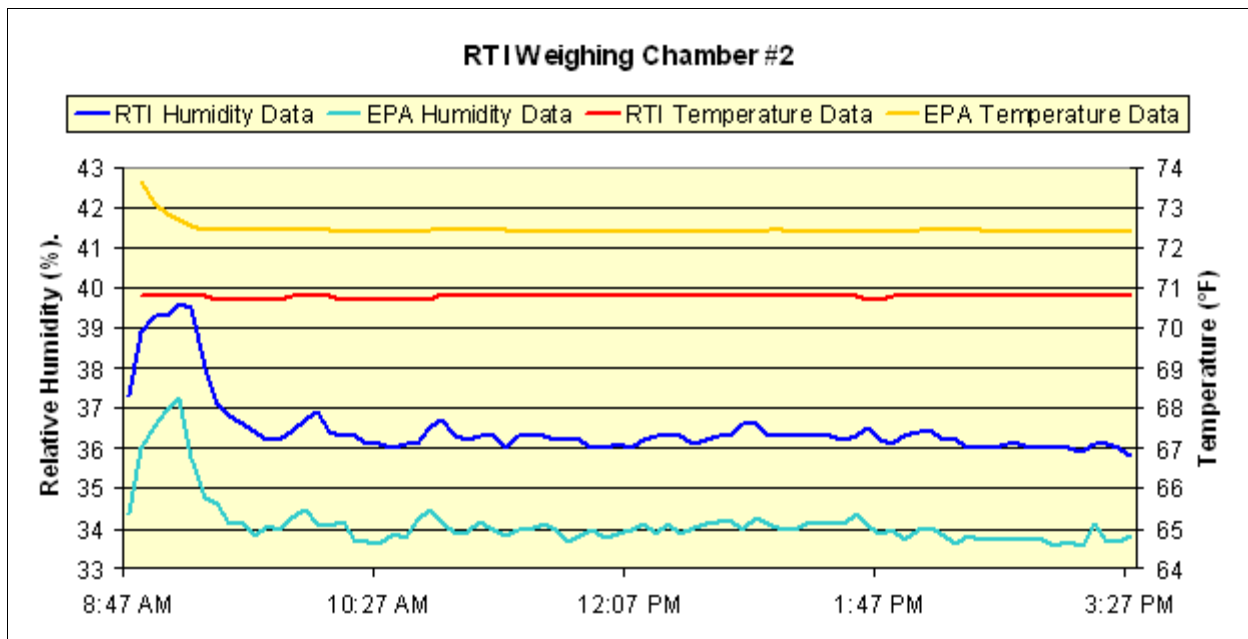


Figure 2

Figure 2 shows the humidity and temperature data collected inside chamber #2. Both loggers show a dramatic peak in RH at about 9 AM. This surge in humidity was probably due to four extra people entering the chamber during this period. Three auditors and the supervisor entered the chamber at approximately 8:45 AM, and remained inside the chamber for about twenty minutes. The graph for chamber #2 shows humidity values measured by RTI's device consistently above those recorded by NAREL's device. The average RH recorded by NAREL's logger was 34.1 %, and the average RH recorded by RTI's device was 36.5 % during the same period.

Figure 2 shows a noticeable difference in temperature values measured inside chamber #2. The average temperature recorded by RTI's logger was 70.8 °F, and the average temperature recorded by NAREL's logger was 72.5 °F. According to RTI's QAPP, their logger is expected to have an accuracy of ± 2 °C (± 3.6 °F). NAREL's logger is expected to have an accuracy of ± 0.5 °F, and it was certified to provide this level of accuracy about one month before RTI's audit. Although difference between loggers can be seen in Figure 2, none of the temperature and humidity discrepancies are greater than RTI's stated measurement uncertainties.

Figure 3 shows one more comparison. Both of NAREL's data loggers were removed from the weighing chamber at NAREL on July 11, one day before the audit at RTI. Before they were removed, both of the loggers were located immediately near the other inside NAREL's chamber. Figure 3 shows the temperature and humidity data that were recorded by both loggers from midnight to about 8 AM at which time they were removed from the chamber and placed inside a small Igloo® container for transporting to the audit. It is important to realize that NAREL's two loggers were not exactly identical, and the most significant difference can be seen in the humidity measurements. The logger that was used to make measurements in RTI's chamber #1 shows an average RH of 35.9 % while the logger used to make measurements in RTI's chamber #2 shows an average RH of 35.5 % for the same time period. If NAREL's data loggers had been switched during the audit so that each device was placed into the opposite chamber, then the RH comparisons would have shown better agreement [by about 0.4 %] for both of RTI's chambers.

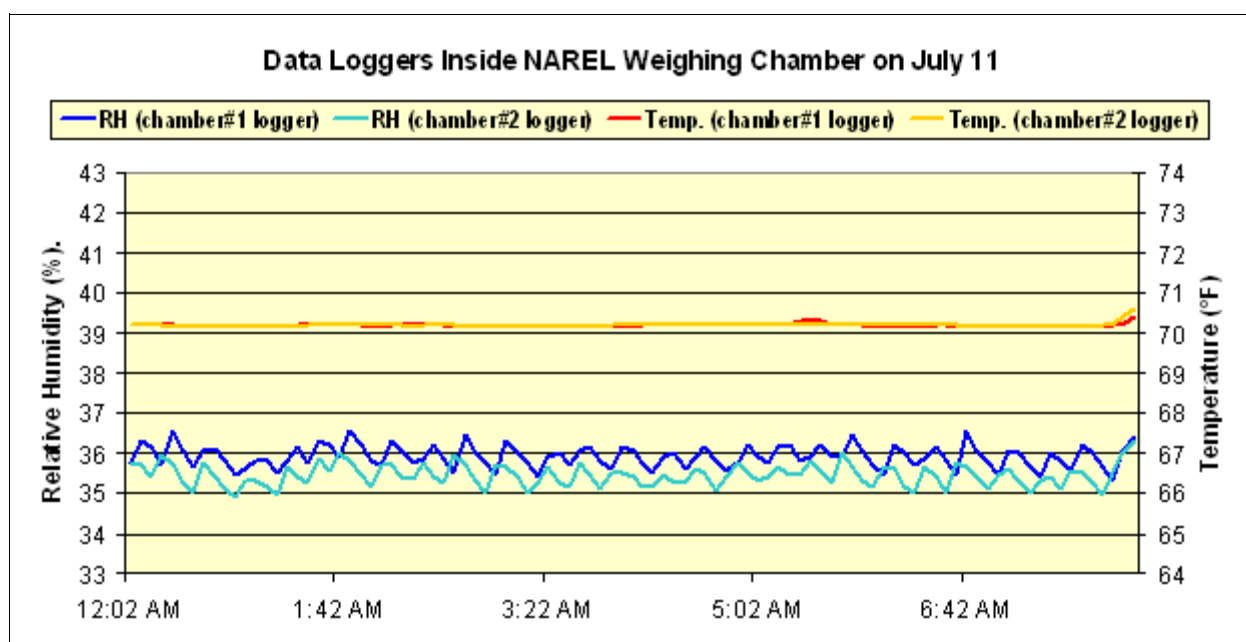


Figure 3

So how good is the temperature and humidity control at RTI? This audit has shown that both chambers were within RTI's stated control limits for temperature (68-73.4°F) and for RH (30-40%) regardless of which device was selected to provide the measurements.

Later during the audit, two Teflon® filters were removed from the SHAL inventory and traveled with the auditors back to NAREL. These two filters were placed into NAREL's weighing chamber for re-equilibration and weighing so that an independent tare mass could be determined for each filter. Those results are presented in Table 2, and excellent agreement was observed for one filter, but poor agreement was observed for the second filter.

Table 2

Teflon® Filter ID	Filter Description	RTI Tare Mass (mg)	NAREL Tare Mass (mg)	Difference (mg)
12227086	Inventory Filter 1	151.324	151.325	0.001
12227075	Inventory Filter 2	151.099	151.069	0.030

NAREL's tare mass for the second filter was thirty micrograms (30 µg) lighter than the tare mass determined at RTI. Effort was made to discover a reason for this discrepancy. The filter identification was verified by checking the bar code label as well as the serial number on the filter itself. Data transcription errors were unlikely since duplicate tare measurements had been made at RTI, and both measurements agreed within one microgram. Four measurements were made at NAREL over the course of eight days, and all of NAREL's measurements agreed within two micrograms. It is possible that a small piece of extraneous contaminating debris was attached to the filter for measurements taken at RTI, and somehow the debris was lost from the filter before measurements were made at NAREL. Other explanations are also possible.

Dialog was initiated between NAREL and RTI to further investigate this significant finding. The auditors learned that corrective actions had been taken by RTI earlier in the year to deal with a defective lot of Teflon® filters. RTI had observed abnormal gravimetric mass results for filters that were supplied to the field sites during March and April of 2005. The problem revealed itself in two ways: (1) a high frequency of negative results was observed in the gravimetric mass results for the trip and field blanks and (2) a high frequency of outliers was observed in the reconstructed mass balance results for loaded filters. Several filters were examined in RTI's optical microscopy laboratory at magnifications of 3.5x to 40x under enhanced lighting. According to RTI's corrective action report, "*crumbs of filter and/or support ring material were found along the support ring. This material flaked easily from the ring with normal handling.*" RTI's report also stated that "*The negative weights may have been caused by loose debris falling off the filters between the initial and final weighings*". RTI's corrective actions included the return of 6000 unused filters to the manufacturer for replacement. RTI also increased their frequency of weighing filters in duplicate. For example, duplicate tare measurements were increased from 10 % to 100 % of the filters, and duplicate post-weighing was increased from 10 % to 30 % of the filters. It may be a coincidence that NAREL's audit finding is very similar to the blank problems described in this corrective action report.

No other deficiencies were observed as a result of this audit. The overall impression of the gravimetric lab was very positive. Earlier in the year RTI's gravimetric lab weighed several samples that were split with NAREL [see reference 2], and all of those results were within advisory limits.

Carbon Analysis Laboratory

Dr. Max Peterson is the technical supervisor of the carbon analysis laboratory located in building 3. Mr. Melville Richards and Mr. Eric Poitras were analysts working in the lab during the audit. Jewell Smiley and Joann Rice conducted this part of the audit. The interviews and inspections were performed to determine compliance with good laboratory practices, the QAPP, and the following SOP [see reference 5].

- *Standard Operating Procedure for the Determination of Organic, Elemental, and Total Carbon in Particulate Matter Using a Thermal/Optical Transmittance Carbon Analyzer.*

New quartz filters must be thermally cleaned before they are delivered to the SHAL, mounted into the appropriate sampler module, and shipped to the field for sample collection. Upon return to the laboratory, each loaded filter must be analyzed using one of the four Sunset instruments set up to run a thermal/optical method specified for all STN samples. The STN method uses a specific heating protocol to thermally remove carbon from the quartz filter material while the optical transparency of the sample is monitored by shining a laser through the sample. The STN method of carbon analysis is described in the RTI's SOP [see reference 5]. RTI currently uses the STN method to report organic carbon (OC) and elemental carbon (EC) the sum of which represents the total carbon (TC). RTI also reports five OC subfractions: OC1, OC2, OC3, OC4, and PyroC. RTI began reporting the OC subfractions in July of 2003 after a new contract was awarded.

Special attention was given to the OC subfractions during the last on-site audit because of concern that the STN thermal protocol might not provide sufficient data quality for the subfractions [see reference 1]. There was concern that the STN method might show poor precision for the

subfractions over time and between instruments. Some of the earliest evidence came from sucrose spikes which are routinely analyzed at RTI as daily calibration checks. The sucrose spikes have shown good precision for the total carbon measurement over time and between instruments, but unfortunately, sucrose shows poor precision for some of the OC subfractions. It was suggested in RTI's last audit report that we need to learn more about the data quality of the OC subfractions. Specifically, we need to learn more about the between-instrument precision. The lab routinely schedules 10 % of the filter samples for a duplicate analysis, but all of the duplicates are analyzed using the same instrument that performed the original analysis. A recommendation was made within the last audit report to change the way duplicates are scheduled so that some of the duplicates are analyzed using a different instrument. Thus far RTI has not implemented this suggestion for the OC/EC lab. As a consequence, the sucrose spikes are the only routine quality control measure of the between-instrument precision.

RTI recently participated in a study that compared OC/EC results from four different labs [see reference 2], and results from this study were discussed during the audit. A sufficient number of PM_{2.5} filter replicates were prepared at NAREL so that each participating lab received an almost identical set of samples, and each set of samples contained blind duplicates. RTI analyzed each filter sample using all four of the Sunset instruments. RTI's results from this study showed good precision for the blind duplicates and good precision among the instruments. RTI's results were virtually indistinguishable from NAREL's results, even when the OC subfractions were compared.

Later during the audit, two quartz® filters were removed from the SHAL inventory and traveled with the auditors back to NAREL. These filters were analyzed at NAREL to determine the amount of total carbon present on each filter. No significant contamination was observed on either filter.

The general impressions of the OC/EC laboratory developed during this audit were very positive. Only one concern was noted. Some of the routine duplicate determinations should be scheduled to collect between-instrument precision data.

X-Ray Fluorescence Analysis

The PM captured onto the surface of the Teflon® filter is not only weighed to determine its mass but is also analyzed to determine its elemental composition using the energy dispersive X-Ray Fluorescence (XRF) technique. The XRF analysis may not proceed before the gravimetric analysis has been completed. Historically RTI has used one of its remote subcontractor laboratories in Oregon to perform the XRF analysis, but since February of 2002, RTI has operated its own local XRF laboratory to provide a larger sample capacity. There are currently two local instruments at RTI and three remote instruments in Oregon that have been approved for analysis of STN samples.

Dr. Bill Gutknecht is responsible for the review of all XRF data, and Ms. Andrea McWilliams is the analyst responsible for operating both of local instruments. They were interviewed by Jewell Smiley and Joann Rice during this part of the audit. The interviews and inspections were performed to determine compliance with good laboratory practices, the QAPP, and the following SOP [see reference 6].

- *Standard Operating Procedure for the X-Ray Fluorescence Analysis of PM_{2.5} Deposits on Teflon Filters.*

The focus of the XRF audit was to discuss those samples that RTI had analyzed as part of a recent inter-laboratory comparison study sponsored by NAREL [see reference 2]. A sufficient number of PM_{2.5} filter replicates were prepared at NAREL so that each participating lab received an almost identical set of filter samples for XRF analysis. NAREL had received the analytical results from all of the participating labs, and had finished comparing the results reported from different labs. All of the labs reported an uncertainty along with every analytical result. Good agreement was observed among the participating labs for most of the elements that were significantly above the reported uncertainty. The most noticeable exception was aluminum. The auditors were anxious to examine some of RTI's raw data spectra, and of particular interest were the spectra from which aluminum results were derived. RTI's spectra that were used to determine the lighter elements contained a significant interference peak which Andrea described as a diffraction peak. The diffraction peak was not fully resolved from aluminum, nor was it fully resolved from silicon. One would expect an interference of this type to increase the uncertainty of aluminum and silicon results. Yet when RTI's uncertainties were compared to those reported from the other labs, RTI's uncertainties were actually smaller. This study has provided some evidence that RTI may be reporting some uncertainties that are too small. Andrea was asked to explain how the uncertainties were calculated at RTI, and she was not certain how some of the components of uncertainty were calculated by the XRF software.

Ion Chromatography (IC) Laboratory

The IC laboratory is located in building 6 where Dr. Eva Hardison is the technical supervisor, and Mr. David Hardison was the analyst on duty during the audit. Both of them were interviewed by Jewell Smiley and Joann Rice for compliance to good laboratory practices, the QAPP, and the following SOPs.

- *Standard Operating Procedures for PM_{2.5} Anion Analysis* [see reference 7]
- *Standard Operating Procedures for PM_{2.5} Cation Analysis* [see reference 8]
- *Standard Operating Procedures for Cleaning Nylon Filters Used for Collection of PM_{2.5} Material* [see reference 9]

The laboratory is equipped with multiple automated Dionex IC instruments and also has access to equipment for cleaning and extracting Nylon® filters. Four IC instruments were set up for anions and two for cations. At the instrument, multilevel calibration curves are established daily, and the calibration is checked by a second source standard. Duplicate injections have been used to evaluate precision, and post spikes have been used to evaluate accuracy. Control charts were available for recent spikes, duplicates, and laboratory blanks.

Later during the audit, two Nylon® filters were removed from the SHAL inventory and traveled with the auditors back to NAREL. These two filters were extracted and analyzed at NAREL to determine trace level ions that might be present on the filters. No ions were detected on either filter above NAREL's method detection limit.

The interviews and inspections made during this part of the audit were very satisfying, and no deficiencies associated with the IC laboratory were observed during this audit.

Sample Handling and Archiving Laboratory (SHAL)

The SHAL is currently located approximately three miles from RTI's main campus. Moving off-campus to this facility was necessary to handle the large number of samples produced by the speciation network. The network currently produces more than 5000 filter samples per month.

The SHAL is organized to be a central point for all laboratory operations. Every sample passes through the SHAL at least twice. Clean air filters are delivered to the SHAL from the analytical laboratories ready to be packaged and delivered to the field sites. Critical bookkeeping is required to insure sample integrity and to make sure that the proper equipment and information is sent to the field in a timely manner. Loaded filters returning from the field are received at the SHAL, removed from the sampler module, logged into the electronic database, and physically delivered back to the analytical laboratories where the final analysis is completed. After the final analysis is completed, each filter sample is maintained inside a refrigerated archive at RTI for up to 5.5 years, and the IC extracts are kept for six months.

The air filter is protected from the time it leaves the SHAL until it is returned from the field. Each air filter must be mounted into an appropriate sampler module to protect it from accidental contamination. Three different types of filters are required for all of the analytical fractions, and four different types of air samplers are currently operated in the field. Different samplers require different filter modules which are expensive and must be cleaned for reuse. It can be readily seen that the SHAL has a critical role for the overall operations. The correct filter must be mounted into the correct module and mailed to the correct field site on schedule. The SHAL maintains direct interaction with the field sites and with the analytical laboratories.

Eric Boswell, Jewell Smiley, Joann Rice, Dennis Crumpler, and Solomon Ricks visited the SHAL during the afternoon portion of the audit. All of the auditors were able to observe a staged demonstration of the filter assembly/disassembled process. This demonstration was planned in advance so that materials would be available. New filters which had been prepared at NAREL were used for the demonstration, and clean Met One SASS modules were supplied by RTI. SASS modules were selected for this demonstration because the majority of states use Met One air samplers at their sites. During the demonstration two Teflon® filters, two Nylon® filters, and two quartz filters were installed into six SASS modules using procedures routinely executed in the SHAL. The modules were immediately disassembled so that the filters could be recovered and placed back into their protective petri slides. Extra filters were brought from NAREL to serve as travel blanks which were not removed from their protective petri slides. All filters were carried back to NAREL for analysis.

Results from the module assembly/disassembly demonstration showed no measurable contamination transferred to the Nylon® filters and no contamination above 0.4 µg/cm² total carbon (4.7 µg/filter) was observed for the quartz filters. Results for the assembled Teflon® filters are shown in Table 3 along with the associated trip blanks and laboratory chamber blanks. No significant level of contamination was transferred to the Teflon® test filters during the demonstration.

Table 3

Teflon® Filter ID	Filter Description	Tare Mass (mg)	Loaded Mass (mg)	Filter Residue (mg)
T05-11430	Assembled Filter 1	145.396	145.394	-0.002
T05-11431	Assembled Filter 2	145.420	145.420	0.000
T05-11432	Trip Blank 1	144.909	144.907	-0.002
T05-11433	Trip Blank 2	145.904	145.904	0.000
T2112375	Lab Blank 1	144.008	144.008	0.000
T2112400	Lab Blank 2	144.511	144.509	-0.002
T2112425	Lab Blank 3	147.536	147.536	0.000

Other Staff Interviews

Dr. R.K.M. Jayanty, Dr. Jim Flanagan, and Mr. Ed Rickman were interviewed by Eric Boswell and Dennis Crumpler with Jeff Lantz observing. The following topics were discussed.

1. Facility and Equipment
 - a. Facility, Equipment, and Support Services
 - b. Security
 - c. Health and Safety
 - d. Waste Management
2. Organizational Structure and Management Policies
 - a. Personnel
 - b. Job Descriptions and Qualifications
 - c. Training Program and Training Records
3. Quality Assurance
 - a. Standard Operating Procedures
 - b. Performance Evaluation Results and Corrective Action Responses
 - c. Previous Audit Reports and Responses
 - d. Quality Reports to Management
 - e. Quality Control Records and Oversight
 - f. Review Process for QAPP's
 - g. Review Process for Client Data Packages

4. Procurement
 - a. Materials and Equipment
 - b. Services
5. Document Control
 - a. Controlled Document Production
 - b. Document Distribution and Tracking
 - c. Revisions to Control Documents
 - d. Retrieval and Disposal of Outdated Documents
6. Computer Management and Software Control
 - a. Personnel and Training
 - b. Facilities and Equipment
 - c. Procedures
 - d. Security
 - e. Data Entry
 - f. Records and Archives

Conclusions

Observations have been made by the audit team to determine RTI's compliance with good laboratory practices, the QAPP, and SOPs. This audit has produced the following findings, comments, and recommendations.

1. Two Teflon® filters were removed from the SHAL inventory during the audit so that NAREL could experimentally re-measure the tare mass already determined at RTI's gravimetric lab. As shown previously in Table 2, NAREL's tare mass was an alarming 30 micrograms smaller for one of the filters.

Comment: This finding may be an indication of serious problems like the bad filter lot that was discovered several weeks before this audit. According to the corrective action report, the bad filter lot produced negative trip and field blanks. The questionable filter would have produced this effect if it had been utilized as a trip or field blank. RTI should continue to monitor the situation and explore potential reasons for the large variability in blank filters.
2. All of the routine OC/EC duplicates are analyzed using the same instrument that performed the original analysis. This practice was acceptable in the past when the daily sucrose spikes were able to provide evidence of acceptable between-instrument performance. Now that OC subfractions are reported, there is no daily QC that provides the necessary assurance of acceptable between-instrument precision.

Recommendation. RTI should schedule some of the routine OC/EC duplicates for analysis using a different instrument. For example, half of the scheduled duplicates could be analyzed using the same instrument, and the remaining duplicates could be analyzed using one of the available instruments that did not perform the original analysis.

3. As stated earlier, the focus of the XRF audit was to discuss those samples that RTI had analyzed as part of a recent inter-laboratory comparison study sponsored by NAREL [see reference 2]. Results from this study showed aluminum to be the most controversial element reported. This study also showed that RTI generally reported uncertainties which were lower than those reported by the other participating labs. A few spectra were inspected and discussed during the audit. Two specific spectra were selected to be included in the final report for the study. Ultimately the final report included examples of the controversial spectra from all of the labs. The spectra from RTI contain a significant [diffusion peak] interference for aluminum and silicon which was not observed in the spectra from the other labs.

Comment: This observation may not be a problem for RTI's analysis since there is no standard method for calculating XRF uncertainties. However, RTI may want to take a closer look at the way uncertainties were calculated for aluminum and silicon during this study. EPA has recently initiated dialog with all of the speciation labs to learn more about the XRF analysis at each lab, and clearly there is diversity among the different labs. Any progress toward standardizing the XRF analysis is a positive step for the speciation program.

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